

Notice of Allowability

Application No.

09/800,520

Examiner

Laura McGillem

Applicant(s)

IBA ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/15/05.
2. ☒ The allowed claim(s) is/are 34, 41-45 and 58-69.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/214,465.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 12/15/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It does not identify the citizenship of each inventor.

The application has been amended as follows:

In the Specification:

In the first paragraph of the specification after the phrase "This is a divisional of application Serial No. 09/214,465, filed January 5, 1999" insert --now U.S. Patent No. 6,022,709--.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The instant claims are drawn to expression vectors which produce a short-lived transcript of a drug-resistance gene, where the promoter transcribes a gene encoding a viral structural protein, or a foreign gene in a prepackaging cell. The claimed invention appears to be free of the prior art. The closest prior art to the claimed invention appears to be Pavalakis et al (U.S. Patent No. 5,972,596, of record) and Newgard et al (U.S. Patent No. 6,087,129). Pavlakis et al teach expression vectors comprising instability regions (INS) from proto-oncogenes comprising such regions both within and outside of the

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coding region, such as c-fos (see column 2, lines 3-14, 56-62, column 12, lines 14-36 and column 36, lines 14-22, in particular). Pavlakis et al teach that the plasmids comprising the instability sequences also comprise an HIV-1 gag gene sequence which was poorly expressed in cells due to the presence of INS sequences (see column 7, lines 46-60, column 27, lines 54-65 and column 15, lines 65-67, for example), which reads on a viral structural protein. Pavlakis et al teach that neomycin can be operably linked to the instability sequence as a reporter to evaluate mRNA stability (see column 12-21, for example). Pavlakis et al does not teach an embodiment where the neomycin resistance gene is operatively linked to a coding sequence comprising an INS such as a c-fos INS. Pavlakis et al does not teach that recombinase recognition sequences are present on the expression vector or that the gag gene is transcribed in a prepackaging cell.

Newgard et al teach a vector comprising a viral promoter, a polyadenylation signal, and a selectable marker or drug-resistance gene, which can be neomycin, puromycin and hygromycin (see column 3, lines 39-45, column 4, lines 36-37, column 28, lines 43-60 and column 31, lines 34-45, for example). Newgard et al also teach that a preferred embodiment of the invention in which the expression construct is a viral vector for the transfer of foreign genes into mammalian cells (see column 31, lines 1-3, for example). Newgard et al contemplate an embodiment of the invention in which the Cre/Lox site-specific recombination system is used to rescue genes, such as drug selection markers, out of a genome (see column 25, lines 12-20, for example). Newgard et al do not teach a vector with a selectable -drug resistance gene having an

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mRNA-destabilizing sequence that produces a short-lived transcript of the drug resistance gene. Newgard et al do not specifically teach the vector for the expression of viral structural proteins in a prepackaging cell.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 34, 41-45 and 58-69 are allowed (now claims 1-18).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD
2/2/2006


DAVID GUZO
PRIMARY EXAMINER